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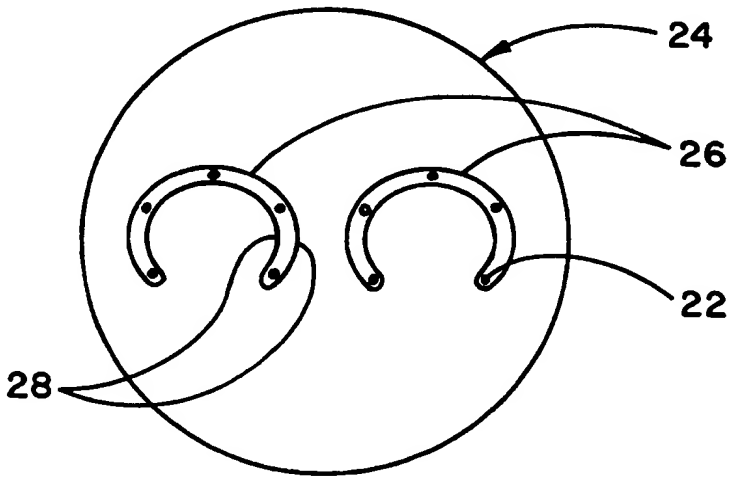
(54) Title: AN ANNULOPLASTY RING

(57) Abstract

An annuloplasty ring having a C-shape and being made of a polymeric material. The annuloplasty ring has a low profile, high tensile strength and a high degree of flexibility. The ring can be used to repair a heart valve annulus using either the "purse string" technique or the "parachute" procedure.



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TITLE OF THE INVENTION

AN ANNULOPLASTY RING

FIELD OF THE INVENTION

The present invention relates to heart valve repair devices, their manufacture and use to restore a dilated heart valve annulus. More specifically the present invention relates to a thin, flexible, high strength, biocompatible prosthesis used to repair and maintain the corrected heart valve annulus size and shape, and a holding and delivery device for the prosthesis.

BACKGROUND OF THE INVENTION

The annulus of a living heart valve is the semi-rigid circumference or ring of tissue surrounding and supporting the valve leaflets. In some instances, the annulus becomes abnormally expanded or dilated with the result that the valve leaflets can no longer contact each other and close properly (valve incompetence). The blood flow through the valve regurgitates (back flows), raising the normal chamber pressures in the heart. For example, mitral valve regurgitation allows blood to flow back into the left atrium during systole. The left atrial pressure may then rise, causing raised pulmonary pressures and pulmonary edema (excess interstitial fluid build up). The higher systemic pressures require a higher workload on the heart. Chronic or continued mitral valve regurgitation may result in congestive heart failure.

To correct a dilated valve annulus, surgical procedures referred to as annuloplasty are performed, which return the expanded circumference of the annulus back to a smaller circumference. By reducing the annular circumference, the valve leaflets are able to fully contact each other, thereby allowing the valve to function properly and eliminating valvular regurgitation. A common surgical repair procedure involves forcing the dilated annulus into a smaller circumference, and while in this reduced diameter state, suturing a support ring onto the natural annulus. The support ring thereby constrains the annulus to the reduced circumference state, and also helps prevent long term re-dilatation of the natural annulus. These support structures, or prostheses, normally remain in the heart as a long term, permanent implant. Two such support devices include those taught by U.S. Patent No. 5,061,277 to Carpentier and U.S. Patent No. 5,104,407 to Lam.

Carpentier describes a planar, flexible valvular support ring, its use and method of assembly. The support ring is comprised of a flexible support section combined with a semi-rigid section. The flexible ring section allows the natural valve annulus to contract with the normal contraction of the heart, while the semi-rigid or stiffer section provides long term rigidity to reduce future dilation of the natural annulus. During the surgical repair procedure, the flexible and semi-rigid portions of the prosthesis are aligned to the stiff and flexible sections of the natural annulus. The Carpentier support ring is of a substantially circular cross section and is comprised of an assembly of metallic and biocompatible polymer elements. The flexible and semi-rigid features of the support ring result from the varying cross sections and stiffness of the metallic elements.

The Lam patent also describes a semi-flexible valvular support ring, comprised of flexible and rigid metallic sections, covered with a biocompatible polymer sheath. To more accurately conform to the natural anatomy, the Lam device is curved or non-planar.

Both of these prior art devices have numerous drawbacks. The support rings of both the Carpentier and Lam patents rely on their embedded metallic members to achieve reliable strength and resistance to long term gradual stretching. These metallic elements have the potential of being in direct contact with blood if the device is damaged. These metallic elements, if exposed by any means to the flow of blood, may evoke foreign body responses or thrombus formation. If not adhered to the metallic surface, this thrombus formation can break free, become an embolus and cause a stroke or organ damage. These same metallic elements also interfere with or limit the suturing positions. The suture needle will be damaged if the needle contacts the metallic elements, impairing the subsequent suturing. Thus excessive care must be taken during the repair procedure to avoid the embedded metallic elements. This requires additional time and also places limits on the suture positions. Although the metallic elements have the desired effect of preventing recurrence of annular dilation, they also have undesirable stiffness. This stiffness inhibits the conformity to the natural anatomy, which can cause excessive stress on the natural annulus and impair the valve function.

Another drawback pertaining to these prior art devices is the large, usually circular cross section. The large cross section further inhibits the conformity of the prosthesis to the natural annulus. The large high profile of the device can also interfere with the natural flow of blood and increase the level of turbulence around the valve. Increased turbulence can cause additional thrombus formation, increasing the danger of stroke or damage to organs.

A further drawback to both of these prior art devices is their inability to be axially compressed. The annulus circumference is decreased as the heart contracts. The support ring used to repair the dilated annulus should therefore have the ability to be compressed axially along with the natural annulus. Due to their metallic elements and large cross

sectional areas, the devices taught by Carpentier and Lam must bend out of their natural plane during compression, which further increases the stress on the natural annulus and device and restricts the natural motion of the annulus.

An additional drawback to these prior art devices relates to their construction. A multitude of components are required to manufacture these devices, including two or more individual wire stiffeners which require complex forming and joining processes. These wires are then coated or sheathed with two or more polymeric coatings, further increasing the process complexity.

PCT Patent Application WO 96/04852 to Northrup teaches the use of an annuloplasty repair procedure and device comprised of individual suture support segments. These suture support segments are metallic and have a pair of predetermined suture holes. The procedure describes passing a suture through the valve annulus and then through a suture support segment. By suturing through the dilated valve annulus with a suture bite larger than the predetermined holes in the suture support segment, the valve annulus will be pinched or compressed in the area under the support device when the suture is secured. A plurality of support devices are spaced, sutured and secured around the annulus, thus reducing the circumference of the dilated valve annulus. Drawbacks to this device include the surface irregularity of the resulting repaired annulus. The annulus with the plurality of metallic support segments must be covered with a biocompatible sheath such as pericardium, which requires additional time to harvest, cut to size and suture into place. The risk of blood contact exposure to the metallic elements is present if the protective sheath is damaged or improperly placed. In addition, the suture spacing in the support device is limited to the predetermined hole spacing, limiting the surgeon's flexibility in determining the suture spacing. Also, due to the stiffness of the support structure, the valve annulus is not axially compressible under the structure, which increases the stress on the annulus and sutures during natural contraction of the heart.

Chang, et al. (*Long-Term Results of Polytetrafluoroethylene Mitral Annuloplasty*, Ann Thorac Surg, 1994; 57:644-647), describe a procedure using an ePTFE vascular graft for the repair of dilated valve annulus. In this procedure an ePTFE graft is tailored to length and sutured to the dilated annulus, using a plurality of suture pairs. Upon drawing up or tightening of the suture the annulus is pinched or compressed, thus reducing the circumference of the dilated annulus affecting repair of the valve. The disadvantages of this procedure include the irregular surface resulting from the kinking of the graft during the tightening of the suture, the relatively large profile of the flattened graft, the resistance to axial compression and the unfilled lumen or inner diameter of the graft.

U.S. Patent 5,450,860 to O'Connor teaches the use of an ePTFE ligament for the plication of tissue, or for the repair of an dilated annulus. This device is essentially a thick

suture which can be threaded through an annulus in a purse string configuration. Once threaded through the annulus, one end of the ligament is secured to the annulus with an additional suture. The second end of the ligament is then drawn tight, reducing the circumference of the annulus. This second end is then secured to the annulus with an additional suture, completing the annulus repair. The ligament can also be threaded completely subcutaneously or completely within the annulus, leaving only the two ends exposed. Drawbacks to this device include the relatively low tensile strength of the device, the inability to perform the "parachute" repair procedure and the damage to the annulus caused by passing a large ligament through the tissue. Thus the need exists for a heart valve annulus repair prosthesis that eliminates the metallic elements, is flexible and conformable to the natural annulus, is axially compressible, has good axial tensile strength, is resistant to creep, has a minimal transverse cross section allowing a low profile, and is highly biocompatible and easy to manufacture. The present invention can meet these needs.

In addition to the prosthesis, other major components of the present invention include a prosthesis holder, a family of valve sizers and a detachable handle capable of engaging both the prosthesis holder and the sizers. These components allow the repair procedure to be performed in an efficient and safe manner. The following descriptions of common repair procedures will clarify the necessity and functions of these additional components. A common annulus repair procedure involves the "parachute" technique. This procedure involves passing both ends of a single suture through the natural annulus, taking a relatively large bite or large gap between the needle penetration points. The two ends of this same suture are then passed through the prosthesis, taking a smaller bite than that of the natural annulus. The prosthesis is normally held away from the natural valve annulus during this procedure to allow easy access to the natural annulus and the prosthesis. The prosthesis must be properly aligned to the natural annulus during this procedure. This suturing pattern is repeated using additional sutures, resulting in several suture "pairs" spaced around the enlarged natural annulus. The prosthesis is then lowered or parachuted down against the natural annulus. As the prosthesis is tied firmly into place against the annulus, the annulus is forced to compress or pinch up between the suture points. Thus the annulus compression is caused by the large suture bites in the natural tissue and the smaller bites in the prosthesis. After all the suture pairs are secured, the result is a reduced annular circumference with an attached prosthesis.

Another common surgical repair procedure involves placing the prosthesis directly against the enlarged annulus and passing a single continuous suture through both the annulus and the prosthesis, in a "purse string" fashion. When the suture is drawn tight, the

annulus is forced into a reduced circumference state. When the suture is secured, the result is a repaired or smaller annulus with an attached prosthesis.

Both of these repair procedures require the use of a "sizer" to approximate and select the proper size of the prosthesis to be used. Progressively larger or smaller sizers are positioned over the natural annulus until the optimum size of the prosthesis is determined.

During both of these surgical repair procedures, it is desirable to constrain and hold the prosthesis in a manner that allows accurate and rapid suturing. In addition the holding device should allow remote positioning, that is, be held by a surgical assistant so as not to interfere with the suturing procedure. In addition the holding device should be easily detachable from the prosthesis. Three such holding devices are taught by U.S. Patent No. 5,041,130 to Cosgrove, U.S. Patent No. 5,011,481 to Myers, and U.S. Patent No. 5,522.884 to Wright.

The Cosgrove patent describes a holding device for use with a fixed circumference annuloplasty ring. The Myers patent describes a device for use with the DURAN™ Flexible Annuloplasty Ring (Medtronic, Inc., Minneapolis MN). The Wright patent describes a device for use with an adjustable drawstring annuloplasty ring. All of these prior art devices have numerous drawbacks particularly in that they rely on sutures to secure the prosthesis to the holder. To allow separation of the prosthesis and removal of the holder, this holding suture must be cut and fully retrieved from the heart during the surgical procedure. All of these devices of the prior art obscure, to some extent, the vision of the surgeon in that it is not possible to readily see through the holder. In addition, the devices of the prior art do not incorporate any suture spacing reference marks. These devices of the prior art are also not compatible with the family of sizers, that is the prosthesis holder handle does not engage the sizers. This requires additional surgical instruments to hold and position the sizers. The device described by Myers has the additional disadvantage of a plurality of holding fingers that protrude over the prosthesis, inhibiting the ability to perform the purse string procedure. Thus a need exists for an annuloplasty prosthesis holder that secures the prosthesis without the use of a suture, is easily detachable, does not impair the vision of the surgeon and has suture spacing reference marks. An additional need exists for a prosthesis holder handle that will also engage the family of sizers. The present invention can meet these needs.

SUMMARY OF THE INVENTION

The present invention provides a heart valve annulus repair prosthesis that overcomes the above-described drawbacks and disadvantages of the prior art. The

annuloplasty ring of the present invention generally has a C-shape and a low profile. In its preferred embodiment it has a high tensile strength and a high degree of flexibility. The devices of the present invention preferably rely on porous expanded polytetrafluoroethylene (hereinafter ePTFE) films, laminated together to form a thin, conformable, high strength sheet. A prosthesis of the desired size and shape is then cut out of this sheet, resulting in a highly biocompatible device made predominantly from a single material. By eliminating the metallic elements present in the prior art, the prosthesis of the present invention is highly conformable to the natural anatomy, is flexible, axially compressible and easy to suture. The sutures can be located anywhere along or across the prosthesis. The laminating of the ePTFE films results in a thin, high strength, creep resistant prosthesis, comprised of a single biocompatible material.

The holding device for this prosthesis clamps the prosthesis on the inner surface, does not rely on sutures for retention and is thus easily detachable from the prosthesis. The holding device is transparent and does not obscure the vision of the surgeon and incorporates suture spacing guides. The holding device also allows either the parachute or purse string procedures to be performed. In addition the holding device is capable of engaging and holding the annulus sizers.

It is an object of the present invention to provide a highly flexible prosthesis that conforms to the natural anatomy.

It is another object of the present invention to provide a device that maintains long term flexibility.

It is another object of the present invention to provide a thin, substantially rectangular cross section prosthesis, that minimizes blood flow turbulence when used as a heart valve annulus repair device.

It is another object of the present invention to provide a prosthesis with high tensile strength, high suture retention strength and resistance to long term creep to prevent future dilation of the annulus.

It is another object of the present invention to provide a prosthesis that is axially compressible so that during contraction of the valve annulus, the prosthesis does not impart excessive stresses onto the natural valve annulus.

It is a further object of the present invention to provide a prosthesis comprised of a highly biocompatible material that minimizes thrombus formation.

It is an additional object of the present invention to provide a prosthesis without metallic structural components or other features that will inhibit or impair the ease of suturing, or limit the positions of the sutures.

It is another object of the present invention to provide radiopaque markers embedded within the prosthesis.

It is an additional object of the present invention to provide a prosthesis holder device that does not rely on sutures for retention of the prosthesis, and is readily removable from the prosthesis.

It is another object of the present invention to provide a holder that does not obscure the vision through the holder.

It is a further object of the present invention to provide a holder that incorporates suture spacing guides.

It is an additional object of the present invention to provide a prosthesis holder handle that will also engage and hold the required annulus sizers.

These and other objects and advantages will become more apparent when considered with the following detailed description, drawings and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A shows the individual plies of the laminating material angularly oriented and stacked together to form a laminated sheet. Embedded within the sheet are radiopaque markers.

Figure 1B shows the laminated sheet with the cut patterns defining the prosthesis shape.

Figure 1C shows a side view of the cut prosthesis.

Figure 2A shows a valve sizer with the trigone alignment marks.

Figure 2B shows the prosthesis supported by the holder with the trigone alignment marks and the suture spacing marks.

Figure 2C shows the handle assembly attached to the sizer, the sizer trigone alignment marks, the natural valve and natural trigones.

Figure 2D shows the handle to sizer (or holder) release feature.

Figure 3A shows the handle assembly attached to the holder which supports the prosthesis. Also shown is the holder to prosthesis release feature.

Figure 3B shows a side cross sectional view of the holder supporting the prosthesis, with the handle assembly detached from the holder.

Figure 3C shows a side cross sectional view of the holder to prosthesis release feature.

Figure 4 shows the handle, holder and prosthesis positioned above the valve to be repaired in a typical parachute procedure.

Figure 5 shows the handle, holder and prosthesis being forced down against the valve to be repaired, in a typical parachute procedure.

Figure 6 shows the handle being removed from the holder during the repair procedure.

Figure 7 shows the holder being removed from the prosthesis at the completion of the repair procedure.

Figure 8A shows a cross section of the prosthesis conforming to the natural non-planar anatomy of a valve annulus.

Figure 8B shows a cross section of the prosthesis in the normal non-compressed state.

Figure 8C shows the prosthesis axially compressing as the valve annulus contracts.

DETAILED DESCRIPTION OF THE INVENTION

The membrane that is used for the annuloplasty prosthesis, can be manufactured from various biocompatible polymeric materials such as polyethylenes (including polyethylene terephthalate (PET)), polypropylenes, polyesters, fluoropolymers, polyurethanes, silicones (polydimethyl siloxanes), etc. Preferred membrane materials are fluoropolymers, including fluorinated ethylene propylene (FEP), perfluoroalkoxy resin (PFA), polytetrafluoroethylene (PTFE), and in particular, porous expanded PTFE.

The preferred membrane used in the present invention is made from layers of film stacked and bonded together to create a laminate. A preferred method of making this laminate is taught by U.S. Patent 5,645,915 (published PCT application WO 96/03457), incorporated by reference herein. The holder assembly can be manufactured from any variety of materials, preferably a highly transparent material such as an acrylic. The preferred material can be sterilized by steam, ETO or radiation processes and does not particulate when stressed or fractured.

The C-shaped annuloplasty ring made according to the materials and methods taught by the present invention may be made to have a low profile wherein the thickness of the C-shaped ring is less than 1.0 mm. It may be made to have a transverse width to thickness ratio of greater than about 5.0. As described in US Patent 5,645,915, the preferred material has great strength in all directions, which allows the annuloplasty ring made from this material to have high tensile strength such as at least about 30.0 MPa, 40.0 MPa, or 60.0 MPa.

The invention will now be described by reference to the figures and non-limiting embodiments. As shown in Figure 1A, sheets or plies 20 of expanded PTFE film are layered and angularly oriented with respect to each other onto a vacuum chuck (not shown). Within the stack of plies, radiopaque markers 22 may be placed onto the plies, in a pattern

matching the final shape of the prosthesis. The radiopaque markers 22 are aligned by a jig (not shown), or are placed by a robotic pick and place system (not shown). These radiopaque markers 22 can be used in subsequent steps to locate the final cut pattern for the prosthesis. Alternate processes for embedding the radiopaque markers include laminating a layer of film with a pre-patterned array of markers or by laminating a thin film of solid radiopaque material.

As shown in Figure 1B, the individual prostheses 26 are cut from the sheet 24, using the radiopaque markers 22 as an alignment guide. The prosthesis can be cut by a laser, following pattern 28, by steel rule dies, or any other suitable means.

As shown in Figure 1C, the resulting prosthesis 26 is of a substantially rectangular cross section and is thin 34 relative to the prosthesis width.

Figure 2A describes a sizer 36 which is used to determine proper prosthesis size. Sizer 36 has trigone alignment marks 38. These marks are positioned over the natural valve trigones during the sizing operation. Also shown is the handle attachment feature 40, which is used to engage the handle.

As shown in Figure 2B, the holder 42 which constrains the prosthesis 26, also has a handle attachment feature 44 which is identical to the handle attachment feature on sizer 36. Thus the handle is interchangeable with both the sizers and the prosthesis holder. Also shown are the trigone alignment marks 46 and the suture spacing marks 48.

As shown in Figure 2C, the handle 50 is engaged into the sizer 36. The trigone marks 38 on the sizer 36 are aligned with the natural trigones 52 of the valve 54 to be repaired. Various sizers are positioned in such a manner until the optimum size is determined. The corresponding size prosthesis is then used for the valve repair. Also shown is a bendable section 56 on the handle so that the sizer or prosthesis holder can be optimally positioned.

As shown in Figure 2D, the sizer 36 can be removed from the handle 50 by compressing release means 58 on the handle.

As shown in Figure 3A, the handle 50 is engaged onto the holder 42 which constrains the prosthesis 26.

Figure 3B shows a cross section of the holder 42, with the prosthesis 26 clamped between the top section 60 and the bottom section 62 of the holder 42. Also shown is the prosthesis release feature 64.

Figure 3C shows the prosthesis 26 being released from the holder 42. By applying a squeezing force 66 onto the release feature 64 (Figure 3B), the clamping force on the prosthesis is removed and the prosthesis 26 can be readily removed from the holder 42.

Figure 4 depicts the initial step of a typical parachute procedure. The handle 50 is engaged onto the holder 42 which constrains the prosthesis 26. The prosthesis 26 is

aligned over the valve 54 and valve trigones 52 by reference of the trigone marks 46 located on the holder 42. Sutures 68 are passed through the natural annulus 70 taking a relatively large bite 72. This same suture 68 is then passed through the prosthesis 26, taking a smaller bite 74 than that of the large bite 72 in the natural annulus 70. This suturing process is repeated, resulting in several sutures, relatively evenly spaced around the prosthesis 26 and the natural annulus 70. The suture spacing marks 48 on the holder 42 assist in achieving uniform suture spacing.

Figure 5 shows the holder 42 and constrained prosthesis 26 being forced down against the valve annulus 70. The sutures 68 are pulled through the prosthesis 26 as the prosthesis is forced against the valve annulus. The prosthesis 26 is aligned to the valve trigones 52 by reference to the trigone marks 46 on the holder.

Figure 6 shows the sutures 68 tied into knots 76, during which the valve annulus 70 is pinched up due to the smaller bites in the valve annulus. This pinching up reduces the circumference of the valve annulus, bringing the valve leaflets closer together and effecting the valve repair. Once the sutures are secured (or whenever convenient) the handle can be removed by simply depressing the handle release feature 58 located on the handle 50.

As a final step, as shown in Figure 7, the holder 42 is separated from the prosthesis 26 by squeezing the prosthesis release feature 64 with forceps 78 or by any other suitable means.

As shown in Figure 8A, the attached prosthesis 26 conforms naturally to the annulus 70, despite non-planarity or differences between individual anatomy.

As shown in Figure 8B, the prosthesis 26 is attached to the natural annulus 70 by the sutures 68. The sutures are secured by knots 76. The prosthesis 26 is shown in the normal or non-compressed state.

As described by Figure 8C, the prosthesis 26 is axially compressible if necessary during systole or contraction 80 of the natural annulus 70. The prosthesis 26 can deform or fold 82 between the sutures 68 and suture knots 76 during compression. When returned to the non-compressed state, the prosthesis will still provide tensile support or protection against re-dilatation of the annulus which would again require surgical intervention. This folding action does not impart any undue stress to the sutures or the natural valve annulus.

Various annuloplasty devices were tested to determine tensile strengths and degrees of flexibility. Tensile tests were performed in accordance with the test methods described in published PCT application WO 96/03457 while flexibility was quantified by calculating the moment of inertia (I) about the central axis and multiplying this value by the modules of elasticity (E). This value of E multiplied by I (referred to hereinafter as EI) quantifies a structural member's degree of flexibility or the magnitude of deflection under a given load. The E values were also determined using the test methods described in US Patent

5,645,915. The devices tested have either relatively high tensile strength with relatively high stiffness, or alternatively have low tensile strength with low stiffness. Thus the devices tested are either strong and stiff, or weak and flexible. The device of the present invention has both desirable properties, i.e., high tensile strength combined with high flexibility.

For example, of the devices tested, the DURAN Flexible Annuloplasty Ring had the highest measured force to break of 15 kg and the highest tensile strength of 20 MPa. However, the same device is very stiff with an EI of greater than 100 MPa(mm^4). The force to break and stiffness is primarily due to the large 3.0 mm diameter of this device.

Conversely, the device with the lowest EI, or most flexible device tested, was the device taught by the O'Connor patent. The O'Connor device had a force to break of only 1 kg, a tensile strength of 15 MPa and a low EI of 8.0 MPa. The low force to break and low stiffness is primarily due to the small 1.0 mm diameter of this device.

By comparison, the device of the present invention has a comparable force to break as that of the DURAN Flexible Annuloplasty Ring, has a higher tensile strength of 60 MPa, along with equivalent or less stiffness than that of the O'Connor device. The device of the present invention can have a stiffness as low as 2.0 MPa(mm^4) while still maintaining adequate force to break and tensile strength. It can thus have a tensile strength of at least about 30.0 MPa, or 40.0 MPa, or 60.0 MPa, in combination with a stiffness or flexibility of 8.0 MPa(mm^4) or less.

While particular embodiments of the present invention have been illustrated and described herein, the present invention should not be limited to such illustrations and descriptions. It should be apparent that changes and modifications may be incorporated and embodied as part of the present invention within the scope of the following claims.

We Claim:

1. An annuloplasty ring comprising a C-shaped ring of polymeric material having a low profile wherein the thickness of the C-shaped ring is less than 1.0 mm.

2. An annuloplasty ring according to Claim 1 wherein the thickness of the C-shaped ring is less than about 1.0 mm.

3. An annuloplasty ring according to Claim 2 wherein the C-shaped ring has a transverse width to thickness ratio of greater than about 5.0.

4. An annuloplasty ring according to Claim 1 wherein the polymeric material is selected from the group consisting of polydimethyl siloxanes, polypropylenes, polyesters, polyethylenes and fluoropolymers.

5. An annuloplasty ring according to Claim 1 wherein the polymeric material is a fluoropolymer is chosen from the group consisting of fluorinated ethylene propylene, perfluoroalkoxy resin and polytetrafluoroethylene.

6. An annuloplasty ring according to Claim 1 wherein the polymeric material is porous polytetrafluoroethylene.

7. An annuloplasty ring according to Claim 1 wherein the polymeric material is polyethylene terephthalate.

8. An annuloplasty ring according to Claim 1 wherein the C-shaped ring has a tensile strength of at least about 30.0 MPa.

9. An annuloplasty ring according to Claim 8 wherein the C-shaped ring has a tensile strength of at least about 40.0 MPa.

10. An annuloplasty ring according to Claim 9 wherein the C-shaped ring has a tensile strength of at least about 60.0 MPa.

11. An annuloplasty ring according to Claim 1 wherein the C-shaped ring has flexibility of 8.0 MPa(mm^4) or less.

12. An annuloplasty ring according to Claim 1 wherein the C-shaped ring has a tensile strength of at least about 30.0 MPa and a flexibility of 8.0 MPa(mm^4) or less.

13 An annuloplasty ring according to Claim 12 wherein the C-shaped ring has a tensile strength of at least about 40.0 MPa and a flexibility or 8.0 MPa(mm^4) or less.

14. An annuloplasty ring according to Claim 13 wherein the C-shaped ring has a tensile strength of at least about 60.0 MPa and a flexibility of 8.0 MPa(mm^4) or less.

15. An annuloplasty ring according to Claim 6 wherein the C-shaped ring consists essentially of porous polytetrafluoroethylene.

16. An annuloplasty ring according to Claim 6 wherein the C-shaped ring consists of porous polytetrafluoroethylene.

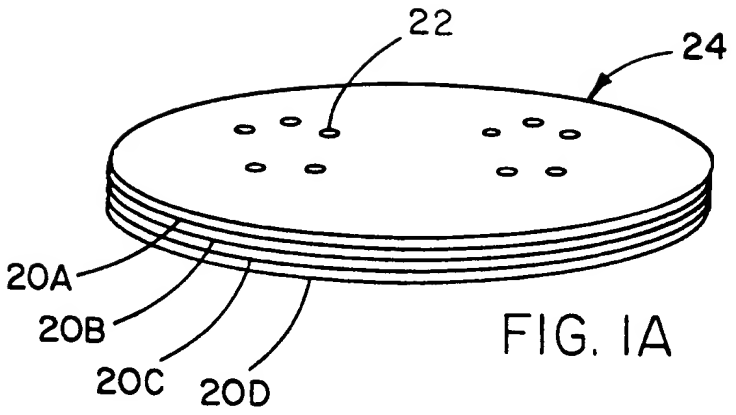


FIG. 1A

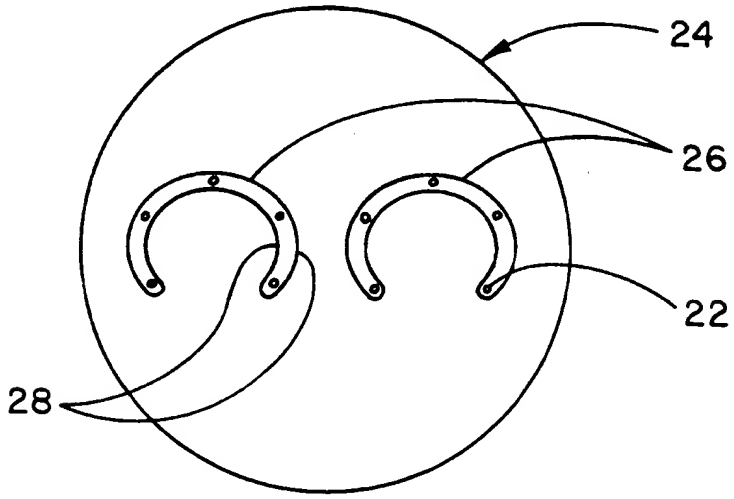


FIG. 1B

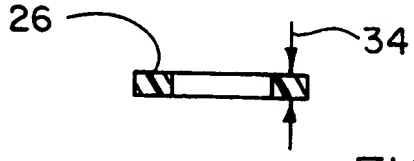
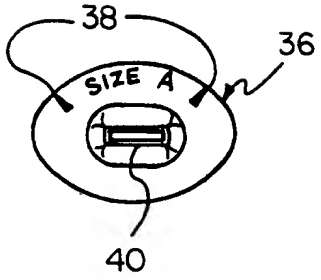


FIG. 1C

FIG. 2A



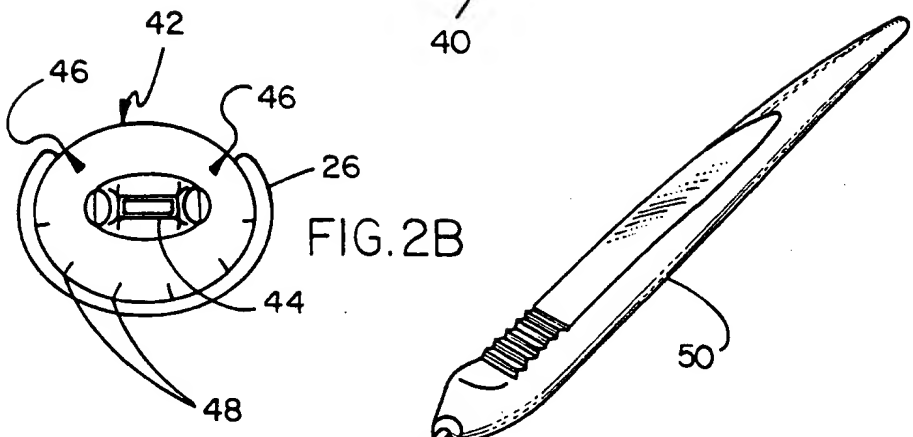


FIG. 2B

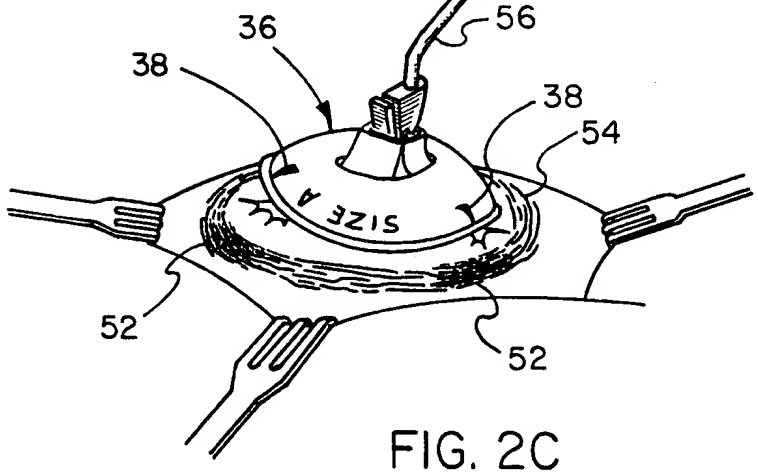


FIG. 2C

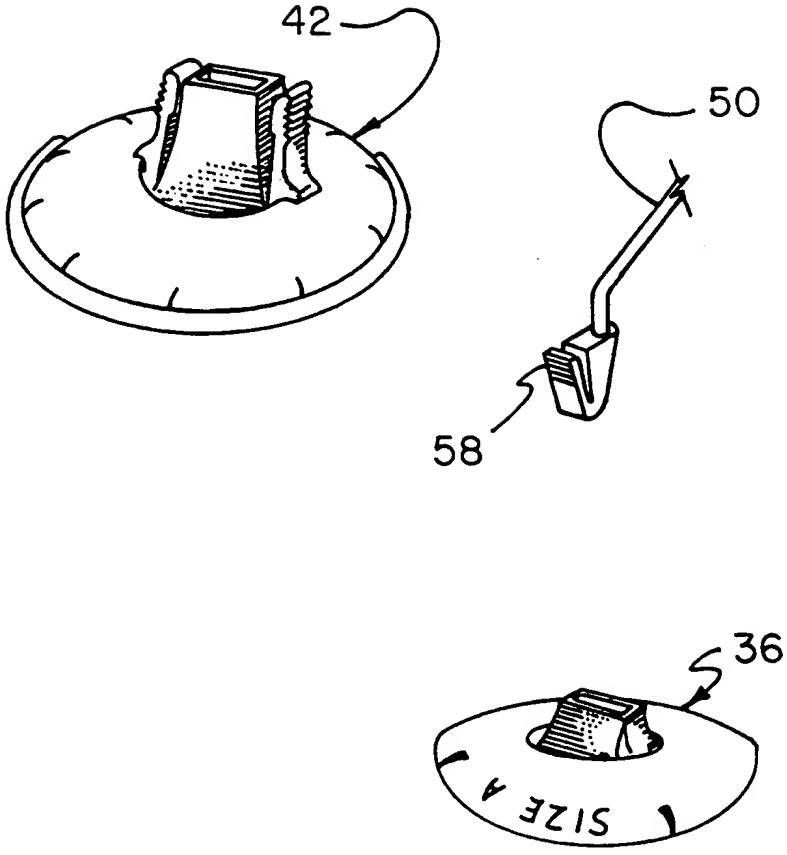


FIG. 2D

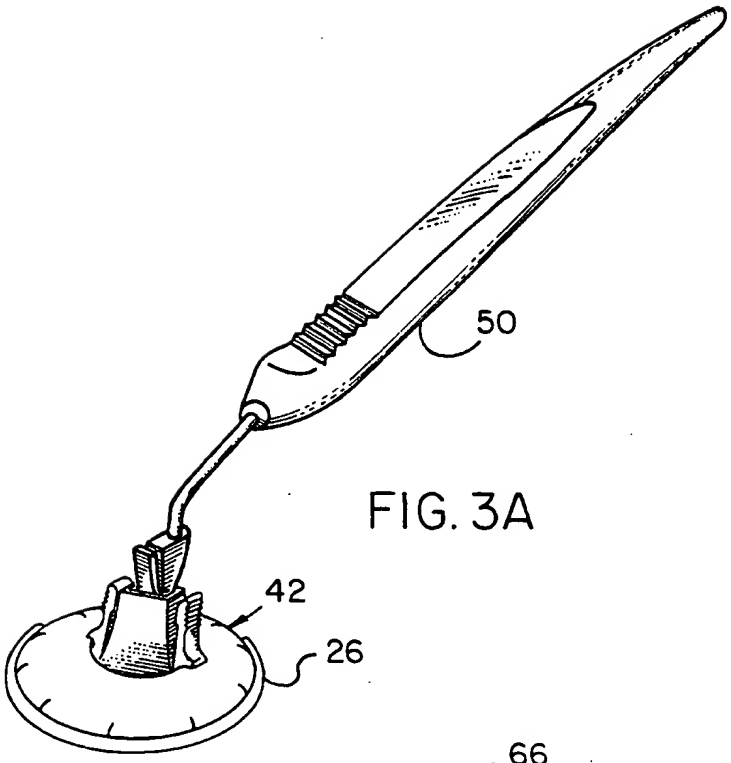


FIG. 3A

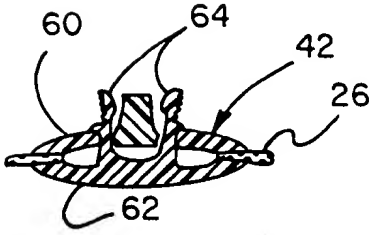


FIG. 3B

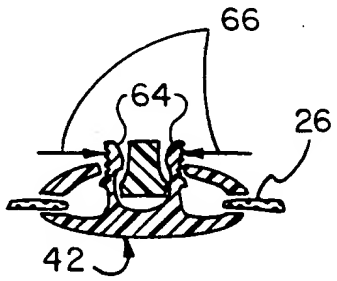


FIG. 3C

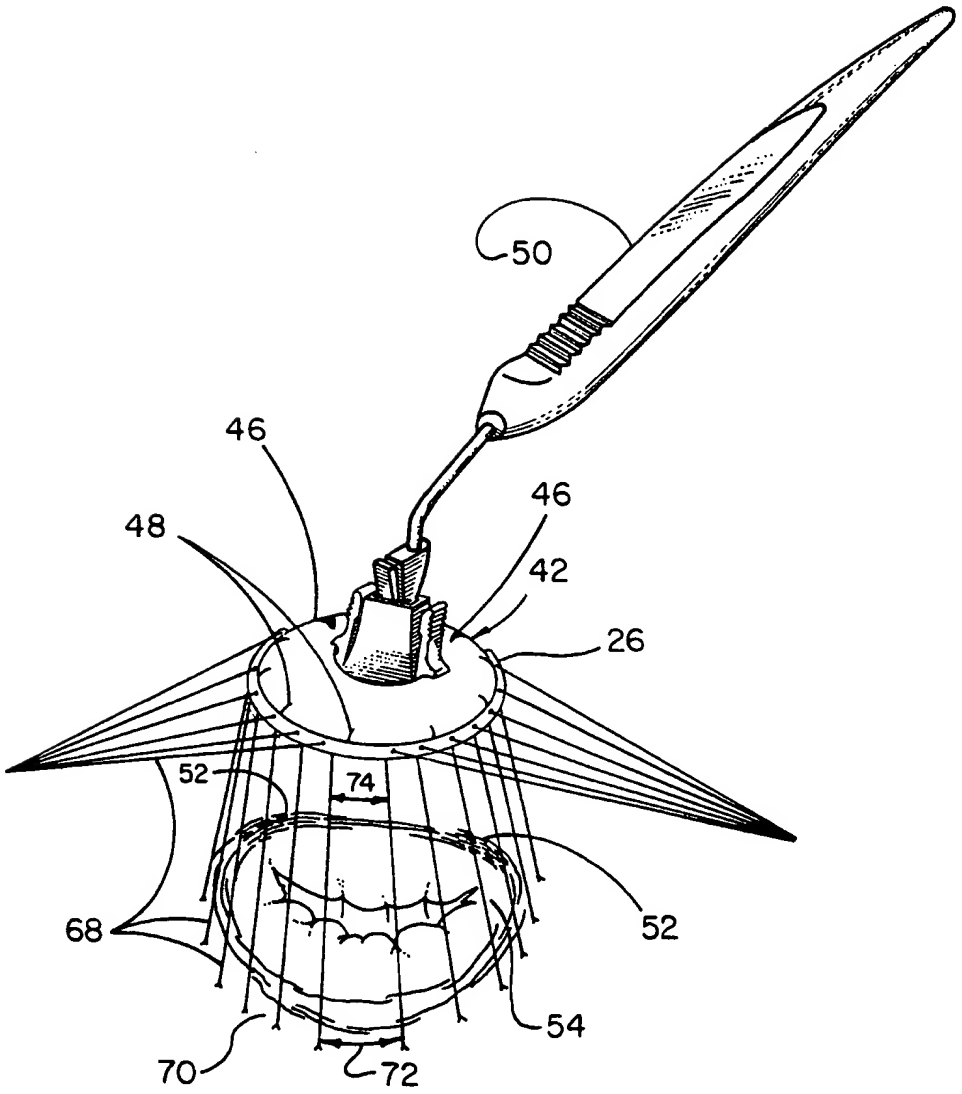


FIG. 4

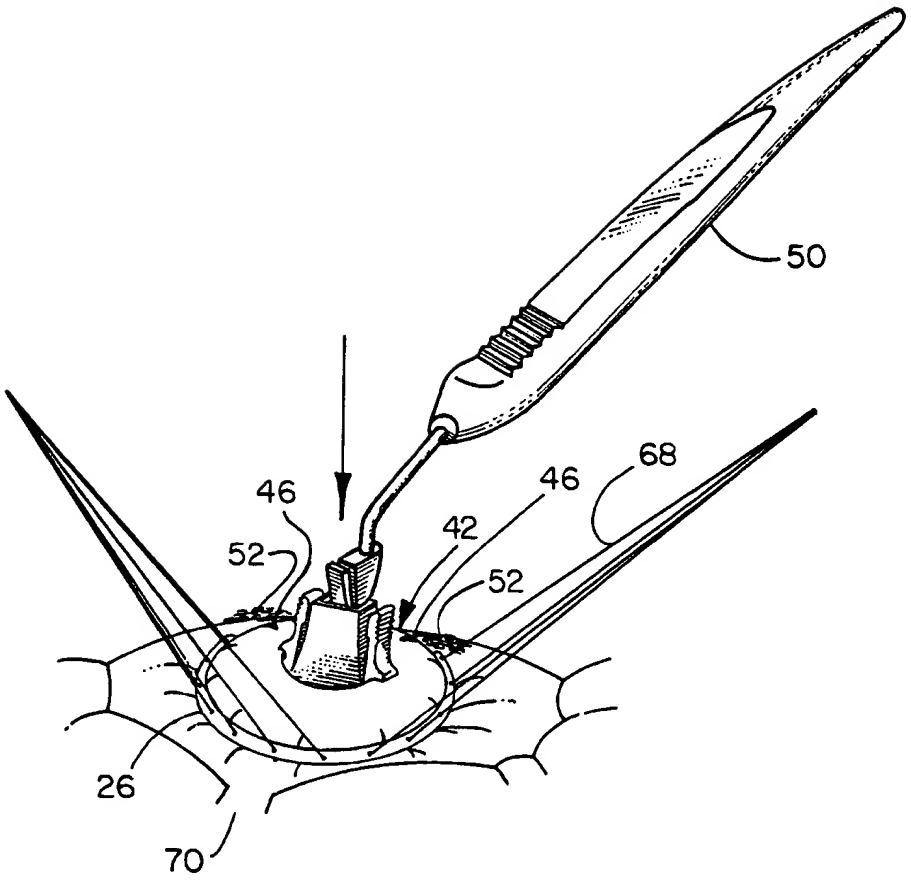


FIG. 5

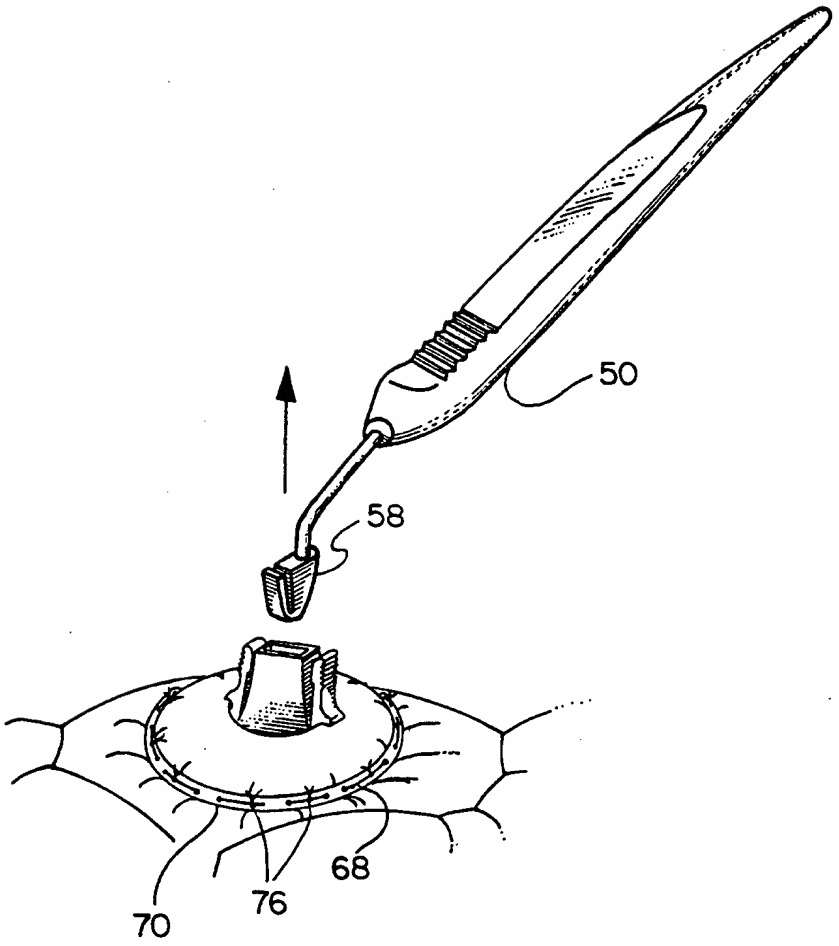


FIG. 6

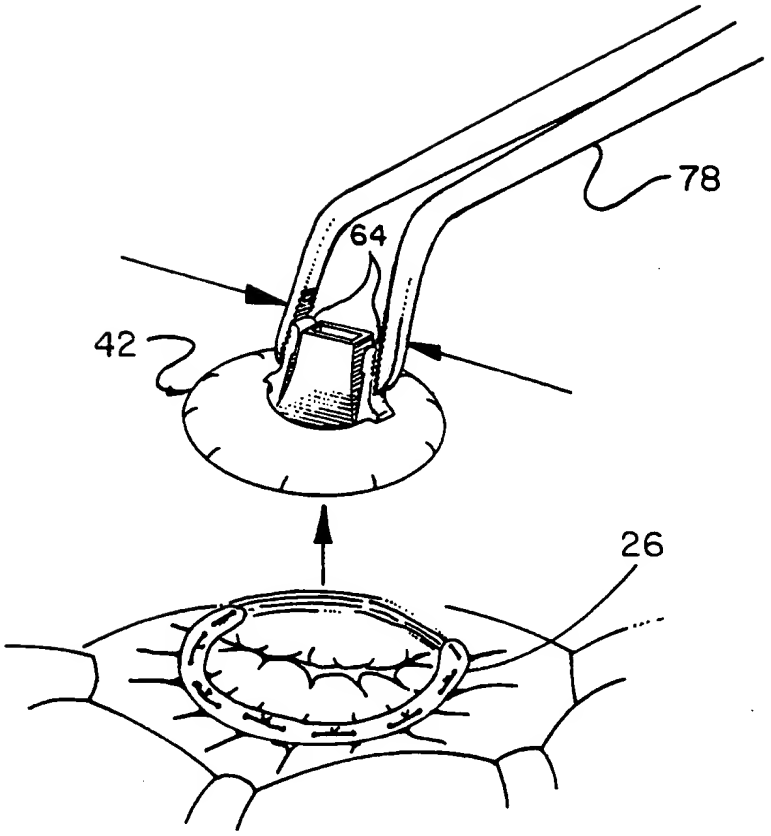


FIG. 7

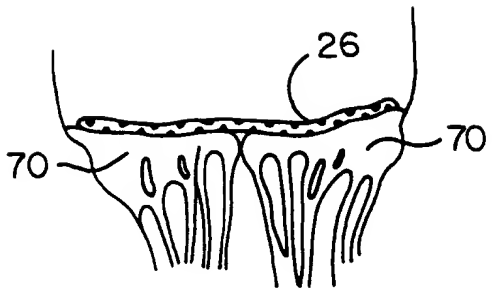


FIG. 8A

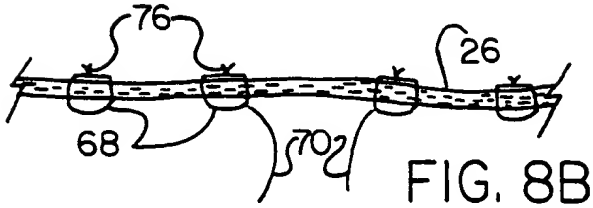


FIG. 8B

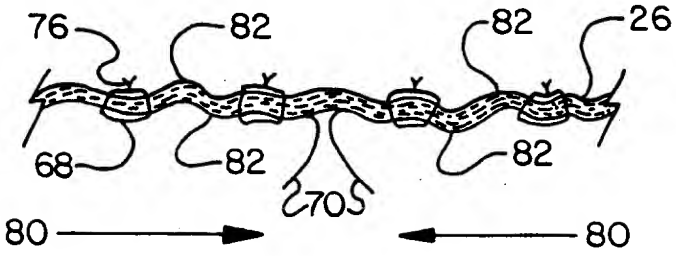


FIG. 8C

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 98/00922

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 338 994 A (MOREA) 25 October 1989 cited in the application see column 4, line 22 - line 31; figure 3	1
A	WO 96 03938 A (BAXTER) 15 February 1996 cited in the application see page 3, line 12 - line 16	1
A	US 4 055 861 A (CARPENTIER) 1 November 1977 cited in the application see abstract	1
A	US 4 042 979 A (ANGELL) 23 August 1977 cited in the application see abstract; figure 1	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 April 1998	12/05/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Papone, F

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/US 98/00922

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